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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,664	01/22/2004	David J. Beebe	282.033	5152

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
11/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Office Action Summary	Application No.	Applicant(s)	
	10/762,664	BEEBE ET AL.	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,17,20,21,24-27,29 and 30* is/are pending in the application.

4a) Of the above claim(s) *9,17,20 and 25* is/are withdrawn from consideration.

5)☒ Claim(s) *24 and 26* is/are allowed.

6)☒ Claim(s) *21,27,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 7/27/2009.

2. In the reply, the Applicant amended claims 21 and 27 and added new claims 29-30. Claims 24 and 26 were previously indicated as allowable. Claims 9, 17, 20, 25 are withdrawn.

3. Thus, claims 21, 24, 26, and 27, 29-30 are pending for examination.

Claim Objections

1. Claim 30 objected to because of the following informalities: Claim 30 lacks a period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 21, 27, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (5848991) in view of Richelsoph (5466261) in further view of Ziaie et al (2004/0248326). In reference to claim 21 Gross et al discloses a microfluidic device (Fig 6) for delivering a drug to an individual, comprising: a body (2) defining a chamber having a fluid impermeable boundary (2b) and including a membrane (8) defining a reservoir (10) and separating the reservoir from the chamber (42, 44); an output cannula (14) having an input in communication with the reservoir (Fig 6) and an output

receivable within the individual (Fig 6); an aqueous solution selectively deposited in the chamber of the body through the fluid impermeable boundary (48 into 44; col 8, lns 66-col 9, ln 19), a pressure source (42) being expandable in response to exposure to the aqueous solution (col 8, lns 66-col 9, ln 19), the pressure source member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the pressure source expands (col 8, lns 66-col 9, ln 19); an adhesive (6); and wherein the adhesive solution is selectively deposited in the chamber by injection (col 8, lns 66-col 9, ln 19).

6. However, Gross fails to teach a a hydrogel member for the pressure source. Richelsoph teaches that it is known to have a hydrogel member (42; col 3, lns 44-col 4, lns 40) defining a pressure source that is expandable in response to communication with an aqueous solution deposited in a chamber for the purpose of incremental pressure control from osmotic swelling in response to water based fluids. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the saline solution in chamber 42 to a hydrogel member as taught by Richelsoph for the purpose of incremental pressure control from osmotic swelling in response to water based fluids. Furthermore, the Examiner notes that such a material substitution for the pressure source is obvious to one of ordinary skill in the art at the time the invention was made because it's a simple substitution of one known pressure source for another known pressure source to obtain predictable results,

7. However, Gross in view of Richelsoph fail to teach a valve defining a chamber and interconnecting the reservoir and the output cannula, the valve movable between a

non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle.

8. Ziaie et al teaches that it is known to have a valve (500; Fig 9-10) defining a chamber and interconnecting the reservoir and the output cannula (Fig 13), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle (Fig 9-10, 13; [0017, 0028, 0143-0147] and discussion of "Hydrogel-Activated Devices"); the valve including a hydrogel microscale valve having a flexible membrane (104) for dividing the valve chamber into a drug flow portion (110) and a trigger receiving portion (103) and a trigger (102) position within the trigger receiving portion of the valve chamber and having a first configuration with the valve in the non-actuated position and a second configuration with the valve in the actuated position (Fig 9) for the purpose of controlling drug delivery either in response to a pre-determined stimulus or for pulsatile delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the reservoir to output needle connection as taught by Gross in view of Richelsoph with the hydrogel activated microvalve as taught by Ziaie et al for the purpose of controlling drug delivery either in response to a pre-determined stimulus or for pulsatile delivery.

Allowable Subject Matter

9. Claims 24, 26 are allowed.

Response to Arguments

10. Applicant's arguments with respect to claims 21, 27 have been considered but are moot in view of the new grounds of rejection.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767